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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,760

Applicant(s)

CROWE ET AL

Examiner

Leon Lankford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 17-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/4/ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of group III in the reply filed on 12/27/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,723,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a method of dehydrating cells with

essentially the same and even overlapping scopes. Any differences in experimental parameters would have been obvious to one of ordinary skill in the art as a matter of routine experimentation with a reasonable expectation of the same or better results.

Claims 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19, 24-27 7 31-33 of copending Application No. 10/721,678. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims a method of dehydrating cells with essentially the same and even overlapping scopes. Any differences in experimental parameters would have been obvious to one of ordinary skill in the art as a matter of routine experimentation with a reasonable expectation of the same or better results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-58 of copending Application No. 10/722200. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims a method of dehydrating cells with essentially the same and even overlapping scopes. Any differences in experimental parameters would have been

obvious to one of ordinary skill in the art as a matter of routine experimentation with a reasonable expectation of the same or better results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-50 of copending Application No. 10/724,246. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims a method of dehydrating cells with essentially the same and even overlapping scopes. Any differences in experimental parameters would have been obvious to one of ordinary skill in the art as a matter of routine experimentation with a reasonable expectation of the same or better results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-47 of copending Application No. 10/724,545. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims a method of dehydrating cells with essentially the same and even overlapping scopes. Any differences in experimental parameters would have been

obvious to one of ordinary skill in the art as a matter of routine experimentation with a reasonable expectation of the same or better results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-42 & 58-61 of copending Application No. 10/889935. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims a method of dehydrating cells with essentially the same and even overlapping scopes. Any differences in experimental parameters would have been obvious to one of ordinary skill in the art as a matter of routine experimentation with a reasonable expectation of the same or better results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please note that the language of a claim must make it clear what subject matter the claim encompasses to adequately delineate its "metes and bounds". See, e.g., the following decisions: In re Hammack, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); In re Venezia 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: In re Steele, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); In re Moore 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); In re Merat, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

In the instant case, it is unclear what the metes and bounds of "dehydrating" (claims 16-22) are wherein the only limit given to the desired range is the lower limit. Without an upper limit or a starting moisture content, it is unclear what amount of moisture removal is required to meet the limitation of "dehydrating"- the scope of the claims is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kortright et al(5059518).

Kortright teaches the loading of eukaryotic cells with trehalose, a notoriously old and well known dehydration protectant, dehydrating the cells (including lyophilization), storing the cells and rehydrating the cells to produce viable cells. Kortright is silent on the moisture content that the cells are dried to, however claims 16-22 are unclear as to what amount of dehydration is necessary so it would appear that Kortright would anticipate the claim subject matter. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicants' moisture contents differ and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to Applicants. *See also, In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) ("the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product"). MPEP § 2112 explicitly states that [T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product - by - process claims. Quoting *In re Fitzgerald*, 619 F. 2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (itself quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 - 34 (CCPA 1977)).

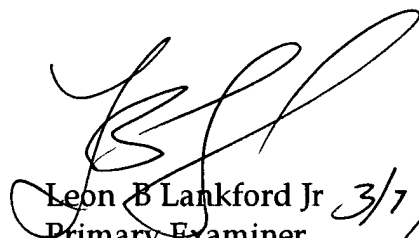
However, even if Kortright does not anticipate the claimed invention, the reference does teach the essentials of the invention as stated above. Kortright and the state of the art at the time the invention was made, recognize that in cellular dehydration/preservation processes there are result effective variables such as the type and amount of preservative, temperature and speed of the process, duration of storage, and moisture content of the cells. One would have reasonably expected success in preserving cells by dehydrating, storing and rehydrating cells when varying the above discussed parameters. One would have been motivated to make changes in these parameters because of that reasonable expectation of success and further because it would have been obvious to optimize said result effective variables.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary. Applicant is reminded that a showing to overcome a prima facie case of obviousness must be clear and convincing(In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter (In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Leon B Lankford Jr 3/1/5
Primary Examiner
Art Unit 1651

LBL